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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/325,603	06/03/1999	ALLAN SVENDSEN	4394.214-US	3011

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NOVOZYMES NORTH AMERICA, INC.  
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NEW YORK, NY 10110

EXAMINER

SLOBODYANSKY, ELIZABETH

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 02/11/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/325,603

Applicant(s)

SVENDSEN ET AL.

Examiner

Elizabeth Slobodyansky

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 81,83 and 87-93 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 81,83 and 87-92 is/are allowed.
- 6) ☒ Claim(s) 93 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on December 23, 2002 has been entered.

The amendment filed on December 23, 2002 adding claim 93 has been entered.

Claims 81, 83 and 87-93 are pending. Claims 81, 83 and 87-92 have been allowed.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 93 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for producing a variant of a parent  $\alpha$ -amylase having an amino acid sequence that is at least 70% homologous to the

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sequences of SEQ ID NOs: 2, 4 or 6 comprising the step of generating a model of said parent  $\alpha$ -amylase using a three-dimensional structure of  $\alpha$ -amylase having the amino acid sequence of SEQ ID NO:13 and having coordinates shown in Appendix 1, does not reasonably provide enablement for a method for producing a variant of a parent  $\alpha$ -amylase comprising the step of generating a model of said parent  $\alpha$ -amylase using a three-dimensional structure for SEQ ID NO:13 shown in Appendix 1 adapted to said parent  $\alpha$ -amylase. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir. 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Factors pertinent to this discussion include predictability of the art, guidance in the specification, breadth of claims, and the amount of experimentation that would be necessary to use the invention.

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In order to practice methods of claim 93 one skilled in the art would need an X-ray crystallographic three-dimensional structure of an  $\alpha$ -amylase having amino acid sequence of SEQ ID NO: 13 having coordinates shown in Appendix 1 and the means and ways to adapt said coordinates.

SEQ ID NO: 13 is made up of residues 1-300 of SEQ ID NO:2 and residues 301-483 of SEQ ID NO:4 (page 7, lines 15-28). Therefore, these sequences are homologous to SEQ ID NO:13 in extent of 70%.

The specification discusses the use of "the HOMOLOGY program from BIOSYM" and "the INSIGHT program" to build the models of *B. licheniformis*  $\alpha$ -amylase (TERM, SEQ ID NO:2) and *B. amyloliquefaciens* (BAN, SEQ ID NO:4) based on the structure of SEQ ID NO: 13 having coordinates shown in Appendix 1 (pages 62-63, Example 1).

However, it is not apparent whether said programs are readily available to the public and what parameters and settings have been used for modelling TERM and BAN. Moreover, there is no guidance as to how to carry out such modeling with any other parent  $\alpha$ -amylase having less homology to SEQ ID NO: 2, 4 or 13 than TERM and BAN. There is no teaching as to correlation between the structure of a parent  $\alpha$ -amylase, the property to be changed and parameters and steps of adaptation to be performed on the structure of SEQ ID NO:13 shown in Appendix 1.

The state of the art is such that it is possible to model a homologous parent  $\alpha$ -amylase structure on the invariant structure of SEQ ID NO:13, but is impossible to

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predict the changes that should be made to said structure in order to be adapted to an unknown effect.

Therefore, one of ordinary skill would require the information regarding the ways and means by which the three-dimensional structure of SEQ ID NO:13 can be adapted for modeling of any parent  $\alpha$ -amylase including SEQ ID Nos: 2 and 4, in order to make an adaptation step required by the method of claim 93(a) in a manner reasonably correlated with the scope of the claim. Without such guidance, the experimentation left to those skilled in the art is undue.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 93 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 93(a) is directed to using a three-dimensional structure for SEQ ID NO:13 shown in Appendix 1 adapted to said parent  $\alpha$ -amylase. The specification does not teach the steps and parameters involved in the step of adaption rendering the metes and bounds of the claim unascertainable.

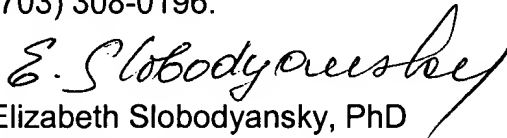
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky whose telephone number is

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(703) 306-3222. The examiner can normally be reached Monday through Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX phone number for Technology Center 1600 is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Center receptionist whose telephone number is (703) 308-0196.

  
Elizabeth Slobodyansky, PhD  
Primary Examiner

February 7, 2003